Testimony
Before the Subcommittee on Research
House Committee on Science
United States House of Representatives

"Tools for Enhancing Small Business Competitiveness in the Dallas Area: A Review of Federal Programs"

Statement of

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Good morning Mister Chairman, Congresswoman Johnson, and Members of the Committee. My name is Jo Anne Goodnight. I am the Coordinator of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs at the National Institutes of Health (NIH) and for the Public Health agencies in the Department of Health and Human Services. On behalf of the NIH, I am pleased to have the opportunity to provide an overview of the NIH SBIR and STTR Programs. My statement focuses on eight areas:

- the role SBIR and STTR plays in the NIH research agenda,
- the types of research NIH supports under SBIR and STTR,
- steps a company needs to take to obtain an SBIR or STTR award,
- features that distinguish the NIH SBIR and STTR programs from those at other agencies
- common strengths and weaknesses in NIH SBIR and STTR applications,
- the effectiveness of these Programs,
- efforts to enhance the Programs,
- And, finally, a few of our NIH SBIR and STTR "success" stories.

The NIH is the principal operating component within the Department of Health and Human Services participating in the SBIR and STTR program. We constitute about 98% of the Department's entire SBIR program activity. In addition, of the 11 participating Federal agencies, our Department contributes the second largest amount of SBIR and STTR funding. In fiscal year (FY) 2003, the NIH SBIR/STTR budget was about $557 million. However, NIH chose to invest more than the minimum statutory requirement, resulting in actual obligations of $564 million. NIH made about 2000 SBIR awards (grants and contracts) amounting to $533 million and 152 STTR awards amounting to $31 million. The State of Texas received a total of 81 SBIR awards (amounting to $19.1 million) and 7 STTR awards (amounting to $2.0 million) in FY 2003. Of these, Dallas received 6 SBIR grant awards and 1 STTR award, totaling nearly $1.4 million. In FY 2003, about 24% of all Phase I SBIR applicants and 44% of all Phase II SBIR applicants were funded; 27% of Phase I STTR and 43% of Phase II STTR applicants received awards.

Role SBIR and STTR Plays in the NIH Research Agenda

The NIH mission is to uncover new knowledge that will lead to better health for everyone. In the course of that mission, NIH uncovers new knowledge about the prevention, detection, diagnosis, and treatment of disease and disability through the support and conduct of biomedical and behavioral research. The SBIR Program, first authorized in 1982, and the STTR Program, authorized in 1992, play a role in the NIH scientific research and development (R&D) arena. Through a competitive, three-phase award system, the Program provides qualified small business concerns with opportunities to propose and develop innovative ideas. The Program encourages small businesses to explore their technological potential and provides the incentive to profit from commercialization of federally-funded R&D projects.

The SBIR and STTR programs, now more than 20 years old, have become fully integrated into the overall scientific programs and goals of the NIH. The SBIR and STTR programs help accomplish the NIH mission to improve human health -- particularly in the goal of translating scientific findings and advances from the "test tube to the medicine cabinet" as well as through

the development of innovative products or services that speed the process of discovery, reduce the cost of medical care, and improve research tools.

We have watched the program evolve through stages of infancy when a Phase I award was $50,000 for 6 months, through some trials and tribulations of adolescence, and into a mature, yet invigorated program. The NIH continues to serve the legislative intent of stimulating technological innovation in the small business research community as well as enhancing collaborative efforts with the academic research community. In addition, we strive to foster and encourage the participation of women, minority and disadvantaged persons in this program, improve the Federal government's dissemination of information about the SBIR program, and increase the private sector's commercialization of technology developed through federal R&D.

Types of research NIH supports under SBIR and STTR

NIH has 23 Institutes and Centers that participate in the SBIR/STTR Program. Each of these awarding components has a research mission with well-defined priorities that address science and health from a specific perspective, disease area (e.g., cancer) or area of concern (e.g., aging). Given 23 different awarding components, it is not difficult to imagine the breadth and depth of science that NIH supports. Some of the topic areas identified in our grant solicitation include, but are not limited to, biodefense, biosensors, nanotechnologies, bioinformatics, imaging technologies, bioengineering, behavioral research, computational biology, telehealth technologies, and proteomics/genomics. While we issue solicitations for projects on specific topics relevant to each Institute and Center (IC), we also encourage small businesses to propose investigator-initiated, mission-related and commercially-viable research ideas. Investigator-initiated ideas are the cornerstone of the NIH research portfolio, including projects supported by the SBIR/STTR programs.

Seven Effective Steps to Obtain an SBIR or STTR Award

A company must take several steps to obtain an SBIR/STTR award:

1) Start with an innovative idea with commercial potential.
2) Understand our agency’s mission and areas of research we support. These are described in the grant and contract solicitations and on the websites of the NIH ICs.
3) Contact relevant program staff to discuss the project and identify a potential “fit” in an IC’s programmatic area.
4) Submit an application for scientific and technical merit review.
5) Discuss with program staff the outcome of the review and obtain guidance for next steps.
6) Meet the eligibility criteria for a small business concern as defined by the Small Business Administration.
7) Demonstrate research integrity.

Features that Distinguish the NIH SBIR/STTR Programs From Those at Other Agencies

There are several features that distinguish the NIH SBIR and STTR Programs from those at other agencies. These features are primarily a result of the degree of flexibility that the Small Business Administration (SBA) has provided to permit functional accommodations to support each agency's mission outcomes.

Award amounts and project periods. What have made our Programs so appealing are the opportunities for firms to propose R&D projects with truly revolutionary outcomes rather than restrict their ideas to projects that can only be conducted under a prescribed amount of time and money. Our experience is that the conduct of certain types of biomedical and behavioral research, such as nanotechnology, clinically-related studies, vaccine development, and drug discovery does not routinely lend itself to prescribed maximum time and dollar levels. These are exceptions, but such projects can be important steps in integrally involving small businesses in some of the most exciting, cutting-edge research. The latitude supported by the SBA encourages companies to propose R&D in fields that have the most biological promise.

Submission dates and amended applications. Other distinguishing features of the NIH SBIR/STTR Programs relate to "closing" or submission dates and amended applications. NIH offers multiple submission dates through the calendar year. In addition, an applicant, if unfunded, may submit up to two revised applications on any of the three submission dates. Entrepreneurs innovate constantly, so in an effort to foster technological innovation, we provide opportunities throughout the year, a minimum of three dates, for small businesses to submit a new or revised Phase I (feasibility study) or a Phase II (full R&D project) application.

Gap funding options. Another feature that distinguishes NIH form other SBIR/STTR agencies concerns the lag time that typically occurs between Phase I and Phase II, and between Phase II and Phase III. To address one of the most difficult issues faced by researchers in the small business community, namely the gap in funding between Phase I and Phase II, we offer a Phase I/Phase II Fast-Track review option in which applicants submit a Phase I and Phase II simultaneously for concurrent review. We realize that the Fast-Track mechanism is not appropriate for all applicants or for all types of research. Therefore, NIH offers alternative avenues such as no-cost award extensions, supplemental awards, and most recently, competing continuation awards, all of which provide bridge funding between the phases. Examples of projects that would benefit from uninterrupted funding include those that involve maintenance of transgenic mice colonies or newly established cell lines and those that include pre-clinical or clinical trials necessary to generate data for FDA approval.

Common Strengths and Weaknesses in SBIR/STTR Applications

All NIH grant applications undergo an external peer review process involving two sequential steps that are required by law. The first step is performed by Scientific Review Groups, composed primarily of non-Federal scientists, physicians, and engineers (from academia and industry) selected for their expertise and stature in particular scientific fields. The second step is performed by the National Advisory Council or Board of the potential awarding component to which the grant application is assigned. Applicants receive a written summary of the

deliberations of the peer review. These analyses are very useful in pointing out the strengths and weaknesses of the proposed research. Some of the most common weaknesses can be categorized in the following areas:

- Lack of innovation
- Inadequately defined test of feasibility
- Unconvincing case for commercial potential and societal impact
- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- Questionable reasoning in experimental approach
- Failure to consider potential pitfalls and alternatives
- Lack of experience with essential methodologies
- Unfamiliarity with relevant published work
- Unrealistically large amount of work proposed

Turning those weaknesses around, common strengths include projects that are truly innovative and have strong commercial potential and societal import, those that include a clear feasibility test as well as realistic and achievable milestones, and those that have a clearly conceived experimental approach that includes sufficient experimental detail, alternative strategies, and appropriate facilities and expertise to conduct the proposed research.

Effectiveness of the NIH SBIR and STTR Program

We are pleased that reports issued previously by the General Accounting Office and the Small Business Administration indicate that the NIH SBIR program has one of the highest rates of commercialization. Results of a recent study commissioned by our agency to evaluate the NIH SBIR Program indicate that through the SBIR Program, small businesses have contributed to the NIH mission of improving human health through biomedical and behavioral research, while enhancing the commercial potential and societal import of their technological innovations. The National Survey to Evaluate the NIH SBIR Program report (PDF) and Appendices (PDF) detail the study and include program results from companies that received Phase II awards between 1992 and 2001. Seven hundred sixty-eight SBIR awardees participated in the study, describing their experiences with the SBIR program and their project outcomes. Even those projects that have not realized the goal of commercialization have generated information for the equally important purpose of contributing to the knowledge base of science through peer-reviewed publications. A few results of that study are worth highlighting:

- Eighty-seven percent of the awardee respondents reported producing 670 new or improved products, processes, usages, and/or services in support of the NIH mission.
- Technological achievements also included 2,203 technical articles, 666 patents, 2,850 conference presentations, 453 copyrights, 252 awards, and 322 trademarks.
- Fifty-two percent of awardees received 1,465 additional Phase I or Phase II awards related to continued development and exploitation of their core technology. Of the 399 awardees who won additional SBIR awards, 40 percent also received non-SBIR funding.

- Eighty-six percent reported success in disseminating SBIR supported technology and information among populations using and receiving health and health care resources.
- Seventy-three percent of awardee respondents reported commercializing new or improved products, processes, usages, and/or services in health-related fields.
- Other evidences of commercialization include 48 drugs and medical devices receiving FDA approval, 281 awardees receiving additional funding from non-SBIR sources, and 436 having ongoing or completed marketing activities.

While commercialization is an important goal and outcome to SBIR/STTR, it is also important not to overemphasize commercialization. There is an element of risk associated with projects funded in the SBIR and STTR Programs. The nature of biomedical and behavioral research is changing and becoming more complex and multidisciplinary. Considering that the eleven Federal agencies that participate in the SBIR/STTR programs have very different R&D needs, NIH appreciates the flexibility that these programs offer to allow funding for both projects that will have near-term commercial potential and those that are far more complex, high-risk or longer-term.

NIH Efforts to Enhance and Streamline SBIR/STTR Programs

NIH has taken steps to enhance and streamline the programs, particularly with regard to bridging the gap between Phase II and Phase III, tracking Program outcomes, and enhancing our outreach efforts.

Bridging the gap between Phase II and Phase III. Certain types of biomedical and behavioral research require clinical evaluation and Federal regulatory approvals before Phase III (commercialization stage) can ever be realized. NIH offers an opportunity to eligible Phase II awardees to seek competing continuation Phase II awards for projects in which the conduct of clinical investigations and Federal regulatory approvals will ultimately be required to realize the potential of the product being researched and developed. A recipient of an NIH SBIR/STTR Phase I and Phase II award normally receives no more than $1 million and 3 years of support. If the intended commercialized product is a medical device, drug or biologic, this amount often represents a small fraction of the funds necessary to complete the studies required for approval and licensing by the Food and Drug Administration (FDA) or other Federal agencies. Yet, the process of moving promising new products from bench to bedside typically takes more than a decade. These are precisely the products with potential to contribute significantly to the economy of the nation and to the health of our nation. It is the intent of the SBIR and STTR Phase II competing continuation grants to support such research and development.

Tracking Program Outcomes. With the completion of the 10-year retrospective study of the NIH SBIR Program, we are looking forward to the development of a dynamic project monitoring system to track outcomes from supported projects. Such a data tracking system will enable NIH administrators to better determine the outputs and outcomes from projects supported through the SBIR and STTR mechanisms. Clearly, commercialization is a major goal of the SBIR and STTR Programs. However, for NIH awardees, there is often a lengthy time of seven to ten or even 12 years before commercialization is realized, a period that routinely extends well beyond NIH support. Thus, commercialization may be one metric for judging program success, but

other measures will be considered as indicators of success, such as published papers, patents, FDA testing/approvals of drugs and devices, and the use of the technology in other research projects.

Enhancing our Outreach Efforts. Communication is an essential element of the NIH application, review and award process. Indeed, it is the common thread that runs through the 7 steps a company needs to take to obtain an SBIR or STTR award. NIH is making efforts to enhance small business competitiveness through numerous grant writing seminars throughout the year. We recently provided such a seminar for a rapidly growing organization called "Women Entrepreneurs in Science and Technology." NIH also participates in the National SBIR/STTR Conferences, at least one of which is annually held in a rural state or a state that has not received a large share of SBIR/STTR funding. Proposal writing workshops are frequently offered as pre-conference sessions at these meetings. On June 23-24, 2004, NIH will host its 6th Annual SBIR/STTR Conference at which over 900 attendees are expected. A major feature of this conference is a grant writing session dedicated to assist potential applicants in preparing a competitive application.

In addition, NIH staff routinely participate in regional and state-wide conferences to provide information about the NIH application, review and award processes and potential funding opportunities. Last June, NIH and about three other agencies participated in the SBIR/STTR/ATP Workshop in Dallas, an event attended by about 140 participants. We are looking forward to a similar event in Dallas to be held May 2004.

In response to the heightened interest of research institutions to learn more about the SBIR and STTR Programs, we have incorporated sessions focused on university-industry partnership opportunities. We will continue our efforts to raise awareness in States, and research institutions within them, to promote the SBIR and STTR Programs. Broad dissemination of information about these Programs is also being accomplished through an NIH SBIR/STTR ListServe message system, encompassing over 11,000 subscribers from the small business community, academia, State entities, professional societies, and others. NIH established a separate ListServe of SBIR and STTR awardees to inform them of important grant-related policies and procedures.

In recent years, many of the agencies participated in a multi-state outreach endeavor called "SWIFT: SBIR -- Where Innovation Focuses Technology". The Federal Program managers traveled by bus, moving to a new State each day, to inform small businesses and research institutions of STTR and SBIR funding opportunities. The first year, SWIFT I "Field of Dreams" tour focused on the Midwest states. In 2001, the SWIFT II "Patriot" Tour focused on northeast states. SWIFT III, held in May 2002, kicked off in Texas and moved eastward through the southern states. Most recently, the SWIFT IV tour visited states in the upper northwest region of the country. This year, September 2004, SWIFT V is expected to tour the states of Michigan, Indiana, Illinois, Missouri, Tennessee, and Kentucky. We are beginning to see the fruits of these outreach endeavors reflected through higher quality applications and increased submissions and awards.

NIH SBIR/STTR Success Stories

A number of NIH SBIR and STTR projects have resulted in significant improvements to our nation's health and in increased productivity of other researchers. I would like to describe several successes in particular that exemplify the kind of SBIR/STTR research NIH supports.

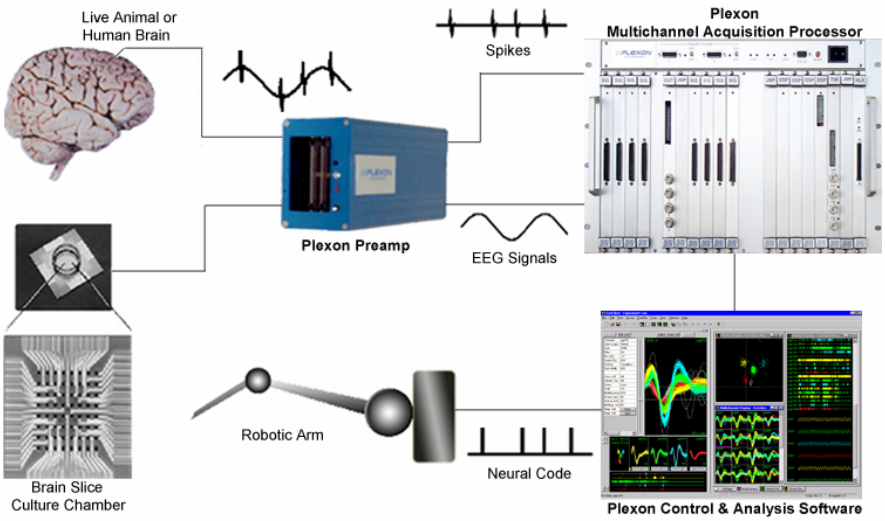
Optiva Corporation (WA)

Looking back more than 20 years to one of the earliest SBIR projects that NIH supported, funding allowed Optiva Corporation to develop a novel power toothbrush, the Dentifrice Dispensing Sonic Brush, which we have come to know as the "Sonicare" toothbrush. In addition to the health benefits, this project resulted in a $300 million business and the creation of over 500 jobs. Optiva was sold to Philips Electronics in 2000.

Plexon Inc. (Dallas, TX)

Plexon Inc. (formerly Spectrum Scientific, a proprietorship), founded in 1984, supplies tools for basic brain and nervous system communication research, neural biosensors for drug and environmental screening, brain-machine interfaces, and neuroprosthetics for the growing neurotechnology industry. Plexon received Phase I and Phase II SBIR funding (1989-1993) from the NIH (National Institute of Neurological Disorders and Stroke) to develop an automated procedure for detecting and separating extracellular neural action potentials (spikes) in real time. These SBIR awards enabled Plexon to develop a unique neural data acquisition system far beyond anything previously attempted at the time. Such an accomplishment has applications to aid physically impaired individuals.

As shown in the diagram below, individual electrodes implanted in the brain or mounted in a brain slice culture chamber often detect spikes from multiple neurons. Each neuron generates characteristically distinct spike waveform shapes. Plexon's hardware and software solutions use advanced pattern recognition and cluster analysis algorithms to discriminate and assign individual waveforms to specific neurons. In addition to providing insight into basic brain function, this technology has broad implications in the development of interfaces for direct brain-machine communication and prosthetic devices for nervous system-impaired individuals.

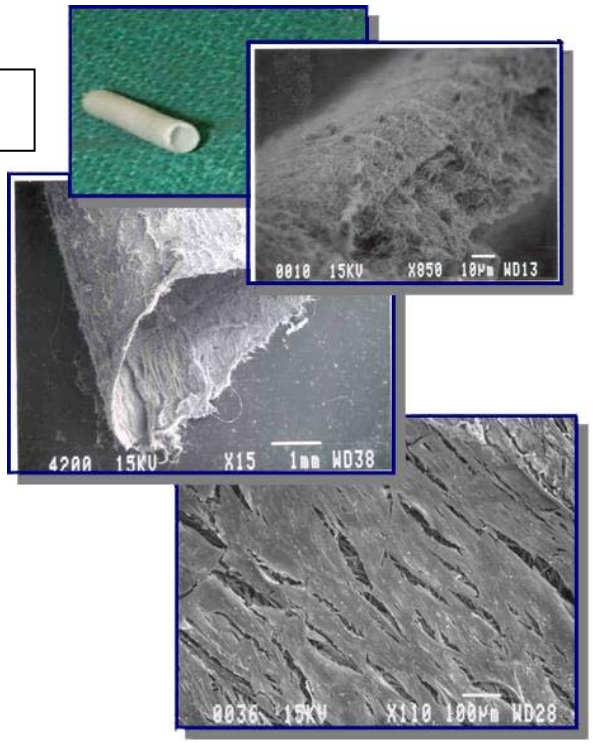


By 1995, Plexon had delivered about 10 systems with most sales to neurophysiologists studying learning, memory, and motor behavior in the nervous system of animals. Up to this time the average number of employees at Plexon was three. Interest in the Multichannel Acquisition Processor (MAP; product name) data acquisition system started to grow, and by 1999 the number of installed systems world-wide reached 60.

Today, Plexon employs 20 people and sales have reached the $3M/year mark. Plexon has grown from a small one-person company to a highly focused team of engineers, biophysicists, and neuroscientists with R&D and technical expertise. Plexon's customers include over 75 domestic and international academic research labs, research hospitals, pharmaceutical companies, and military research labs. The company was recently named as a participant of a $26 million contract to Duke University by the Defense Advanced Research Projects Agency (DARPA) for the development of next-generation brain-machine interface technology. Joint R&D activities are also being conducted with the University of North Texas, California Institute of Technology, Massachusetts Institute of Technology, Vanderbilt University, University of Michigan, Oregon Health & Science University, and others. Company president, Harvey Wiggins, notes, "We have funded our own growth from sales and never used VC or other equity funding. The number of installed systems is above 250. Plexon is the primary brain interface equipment supplier to the major neuroprosthetics research groups in the US."

NanoMatrix Inc (Dallas, TX)

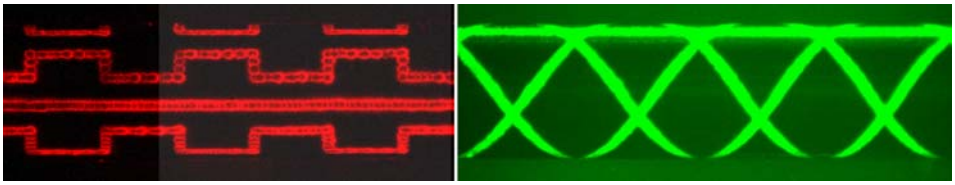
NanoMatrix Inc. and collaborators at Virginia Commonwealth University have received SBIR funding from NIH to use a process called electrospinning to produce a biological and biochemical environment that biomimics that found in normal tissues and organs. The Company's core technology of electrostatic spinning of connective tissue proteins is aimed at mimicking the three dimensional architectural structure that is essential for the body's natural growth and repair processes. For example, Dr. Gary Bowlin, bioengineer at VCU notes that "patients do not always have spare veins for bypass surgery, and even when they do, complications can arise due to rejection. What is needed is an "off-the-shelf" blood vessel of known size and characteristic. The new technology would enable natural human blood vessels to be grown from collagen. Collagen is a natural substance in the body, so cells are in a happy environment and start to grow." The technology was licensed to NanoMatrix for further development. In addition to the cardiovascular applications, this potentially revolutionary technology offers numerous other possibilities --for diabetic patients who often lose blood vessels due to vascular disease, for skin replacement, and for bone regeneration. The following link provides a video that demonstrates the potential of this technology for living coronary artery:
http://www.nanomatrix.biz/demo.asp



Tissue Engineered Products

MicroFab Technologies, Inc. (Plano, Texas)

MicroFab Technologies, Inc. has used SBIR funding to develop and commercialize new technology aimed at enabling high-payoff applications for microdispensing and precision printing of bioactive materials (DNA, proteins, reagents) and other materials used in biomedical device and diagnostics manufacturing. The figures below illustrate biosorbable polymer conduits for nerve regeneration (1mm diameter) and 1mm stainless steel tubes that mimic stents (for cardiac artery implant) printed with a polymer/drug coating (fluorescent die used).SBIR funding from NIH and other federal agencies has led to both direct and indirect commercialization of biomedical applications. Direct commercial success includes sales of equipment for DNA array manufacturing and instrumentation for proteomic discovery. Indirect commercialization success includes application of equipment and processes developed in a tissue engineering project (nerve regeneration conduits) to coating of stents with polymers and drugs for six commercial companies.



Biosorbable polymer conduits (1mm diameter) for nerve regeneration.

1mm stainless steel tubes that mimics stents for cardiac artery implant

Conclusion

Thank you for the opportunity to describe how NIH has utilized the Programs and benefited from them. I would be pleased to answer any questions you may have.

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Ms. Goodnight currently holds the position as the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Coordinator of the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS) Public Health Service. She has held this position, which is located in the NIH Office of Extramural Research (OER), Office of the Director, since March 1999. Prior to joining OER, she served in positions encompassing research, program administration and program management. During nearly 20 years of Government service she has held positions in the U.S. Department of Agriculture (USDA), the Food and Drug Administration, and now the NIH. As part of her Virginia Tech education (1978-1983), she spent four years conducting research as a Cooperative Education student at the USDA's Animal Parasitology Institute. While at NIH, she has been a part of the National Cancer Institute's (NCI) Intramural Research Program as a research scientist (1989 - 1994) and the NCI's Extramural Research Program (1994 – 1999). As an intramural scientist, she published over 20 studies about the selective involvement of Protein Kinase C in differentiation and neoplastic transformation. She joined the NCI's Extramural Research Program in 1994 where she served as a Special Assistant to the Director, Division of Cancer Biology and Program Director for SBIR/STTR grants that supported studies in the field of cancer biology, cancer genetics, and cancer immunology as well as the SBIR/STTR Program Policy Coordinator for the entire NCI. She was appointed as the NIH SBIR/STTR Program Coordinator in 1999 where she continues today.

She was intimately involved in the development and implementation of the NIH SBIR/STTR Fast-Track Program and continues to develop other programs that assist the small business community in commercialization of their technologies. She has been an invited participant in numerous SBIR/STTR Conferences to discuss funding opportunities for small businesses through the NIH. She also has provided written and oral testimony at Congressional hearings related to the reauthorization of the SBIR and STTR Programs.

Ms. Goodnight has received several national awards including an NIH Merit Award (1998) for her "exemplary contributions in the administration and coordination of the extramural research programs of the Division of Cancer Biology," a Tibbetts award (2002) from the Small Business Administration for her "leadership role in making the SBIR and STTR programs more accessible, more relevant, and more effective," and an NIH Merit Group Award (2003) in "recognition of outstanding performance and service to the National Heart Lung and Blood Institute's SBIR Evaluation Group."

Ms. Goodnight received a Bachelor of Science degree in Microbiology from Virginia Tech in 1983.